K112334
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Refine USA. LLC
340 3rd Avenue South, Suite C
Jacksonville Beach, Florida 32250
(866) 333-6858
FAX (888) 842-0395
Cell (904) 629-0395

510(K) SUMMARY

In compliance with 21 CFR 807.92(a)(1):

Premarket Notification submitter:

Company Name:	**Refine USA, LLC**
Company Address:	340 3rd Avenue S., Ste. C, Jacksonville Beach, FL 32250
Contact:	Brian Smith, President
Preparation Date:	August 8, 2011

Device Name – as required by 807.92(a)(2):

Trade Name: **Vein-Gogh™ instrument**

Common/Classification Name: ***Electrosurgical cutting and coagulation device and accessories***

Classification Regulation: **21 CFR 878.4400**

Device Class: **Class II**

Product Code (Procode): **ONQ**

LEGALLY MARKETED PREDICATE DEVICE – as required by 807.92(a)(3)

The **VeinGogh** instrument is substantially equivalent to the presently marketed **Veinwave/TC3000** device manufactured by **Newlands Clinical Trials, Ltd.**, Bolton, United Kingdom, and cleared under **K083352**.

DEVICE DESCRIPTION – as required by 807.92(a)(4)

The **VeinGogh** instrument is intended for the treatment of lower limb spider vein or telangiectasia by thermocoagulation. Users could wear a magnification aid to ensure adequate vision of the treatment area. The user could wear a face shield and gloves as indicated by office practices. The user inserts the needle point in a telangiectasia at a right angle to the vein after setting the instrument's control panel setting of time and pulse or using the instrument's Auto-Pulse functionality. Pulses are intended to be created every 2-3 mm along a vein. The user should clean the needle point frequently between vein insertions with a sterile compress.

The instrument's regulated, small, high frequency current is delivered to the vessel, in a process called "Ohmic Thermolysis," during which the electrical resistivity selectively thermocoagulates small blood vessels using microbursts of high-frequency electrical energy delivered into the vessel. This Microburst Technology™ of fixed amplitude energy within the vessel is converted to heat instantly, coagulating the blood and collapsing the vessel wall. The pulse train encompasses sharp, precise peaks to minimize the risk of damage and deliver consistent results.

The high frequency current is delivered into each vessel through the sterile needle as positioned and inserted by the medical professional. Trained medical professionals can deliver fast, immediate results, which are consistent and repeatable, with little or no discomfort to the patient.

Experienced medical professionals can treat vessels up to 0.3 mm throughout the body. Typically, only a single treatment is required. Multiple spider veins or telangiectasias are treated subepidermally along each veins length, typically every 2-3 mm.

The instrument has a foot switch that is used to cause the instrument to send one pulse with each pressing of the switch. The instrument also has a Ballet Needle holder and uses single use Ballet K3 and K2 stainless steel and gold needles, which are not intended for reuse. The instrument is designed to accommodate needle holders and needles which are equivalent to Ballet Needle Holders and Needles, specifically, those products having the same or similar labeling and listed by their manufacturer under the same regulation and product code.

The instrument has firmware that interacts with the Control Panel push buttons to provide the professional user with operational controls. The firmware cannot be edited or changed by the user.

No bandage or other treatment of the thermocoagulated area is required. Typical treatment times are under 20 minutes and the treatment area (40-50 cm) may receive 300 to 600 impulses during a treatment.

The instrument is not designed to treat feeder vessels or larger vessels deep beneath the skin's surface.

The instrument's dimensions, 16.1 in wide x 13 inches deep x 5.9 inches high and weight, 5.7 pound, allow the device to be used in small or large medical offices on any convenient flat surface. The instrument is intended to be moved in a safe and effective manner, such as movement from one room to another in a medical office or clinic environment.

The instrument is powered by a grounded 120 Volt power source from a wall or floor electrical receptacle. The electrical components are intended to be safe and effective and easily accessed by a qualified technician for any appropriate replacement or repair.

The **VeinGogh** instrument has a 4MHz frequency wave output, and a maximum voltage output of 205Vpp +/-10%.

Microburst Technology is a Trade Mark of Refine USA, LLC, Jacksonville Beach, FL

INTENDED USE - as required by 807.92(a)(5)

The instrument is intended to be used by physicians, physician's assistants (PA) and other physician staff under the direction of a physician trained in the removal of telangiectasia and spider veins on the lower extremities of adults. The instrument is not intended to be used on children.

TECHNOLOGICAL CHARACTERISTICS – as required by 807.92(a)(6)

The **VeinGogh** instrument operates in a typical healthcare professional's office from a standard, grounded 120 Volt AC wall or floor receptacle. The instrument can also be provided to operate at 240 V AC.

The instrument has an allowable environmental operating and storage temperature range of 50 – 90°F and a humidity range of 20-80% (without condensation).

The instrument's desktop footprint is approximately 16" (w) x 13" (d) x & 5.9" (h) and weighs 5.7 pounds and is intended to be placed on a sturdy, flat surface convenient to the patient's location.

The instrument's case/exterior finish allows for dusting and disinfecting.

The **VeinGogh** has a maximum age output of 205 Volts point-to-point (+/-10%) and a 4MHz wave frequency which is delivered as a pulsed output through sterile high frequency epilator needles and needle holder, (Ballet or

equivalent). Typically, Ballet K3 or K2 insulated needles are held in a Ballet Needle holder or equivalent needle holder.

The high frequency epilator needles and needle holder, (Ballet or equivalent) specified are single use only and are not intended for reuse.

The Ballet Needles are listed as a Class I instrument, Product Code KCW by their manufacturer, Ballet Technologies, Ltd. [http://www.balletneedles.com/], 2 Horsebridge Cottages, Horsebridge Common, Ashurst, W. Sussex, UK BN44 3AL, phone +(44) 1903 816 764, Email: Ballet.Technolgies@hotmail.com. Ballet's U.S. distributor is Synoptic Products, 336 Baker Avenue, Concord, MA 01742, phone (978) 287 -728

The **VeinGogh** instrument has a control panel that interacts with its firmware and allows the operator to control:

- Standby/RUN
- Amplitude Power or intensity as a relative % of the nominal 205 Volt peak to peak +/-10%
- Pulse – number
- Auto on
- Auto off
- Time
- Pulse as a range – 0.1 second up to 0.8 second
- Reset for resetting the time and number of pulses

Overall, the technological characteristics of the **VeinGogh** instrument are either identical or very similar to the predicate device. The **VeinGogh** instrument does have a few new technological characteristics not found in the predicate device. These differences are detailed in the "**Product Comparison Table**," below.

PRODUCT COMPARISON TABLE		
Characteristic/Function	**Veinwave device (predicate)**	**VeinGogh Instrument**
Intended Use for Device	Thermocoagulation	Thermocoagulation
Design Specifications	Similar to submitted device	Similar to predicate device
Classification Name, Number & Product Code	Same as submitted device	Same as predicate device
Operational Environment	Same as submitted device	Same as predicate device
Performance Testing Results	None referenced in 510(k) Summary	Referenced in 510(k) Summary
Certified to IEC 60101-2-2 Edition 5.0 2009-02 Medical Electrical Equipment Part 2-2	Makes no Claim	Yes
UL 94 Flammability testing	Makes no Claim	Passed
Finished Device Dimensions - Top	38 x 53 x 17 cm	41 x 33 x 15 cm
Finished Device Dimensions - Bottom	32 x 32 cm	33 x 27 cm
Finished Device Weight	6.6 kg	2.6 kg

PRODUCT COMPARISON TABLE		
Characteristic/Function	**Veinwave device (predicate)**	**VeinGogh Instrument**
Finished Device Construction	Bottom section is made of steel & the top section is made from injection molded plastic	Enclosure is made from fiberglass filled resin & internally coated with conductive metallic layer for EMC protection
Power Supply	In-house designed – 100V Output	OTS Medical Rated Astrodyne MKK 40D-24 (24V Output)
Discrete Power Supply for Safety Isolation	Yes	Yes
Isolation Capacitor in Series with Treatment Connection	Yes	Yes
High Voltage Rated "Y" Type Capacitor	Yes, Y-Type	Yes, Y-Type
Capacitor Used	22nF (~20x leakage)	1.1nF
Dual Capacitors	No	Yes – failure protection
Typical Maximum Output Voltage	500 V Maximum	205 V Maximum (+/-10%)
Output Waveform Frequency	4MHz	4MHz
High Voltage Pulse Generator	Yes	Yes
Type of Generating Circuit	Fly-back Type	Fly-back Type
Return Electrodes	No	No
Patient Isolation from Mains	Internal Isolation Capacitors in Series with the output signal connector	Internal Isolation Capacitors in Series with the output signal connector
Neutral Connection to Mains	Yes	Yes
Chassis Connector	4mm Banana-type receptacle	Identical
Foot Switch	Yes	Yes
Device Console	Proprietary to Device	Proprietary to Device, but similar
Embedded Controller Board	Yes	Yes
Firmware	Proprietary to Device	Proprietary to Device
LCD Display/Type	Yes/Monochrome	Yes/Color
Start-up "splash" screen	Display's Device name, SW version	Display's Device Name, SW version
Display Device Logo	Displays VEINWAVE name	Display's VeinGogh Name/Logo
Display of "power" of the voltage wave (Vpp) as a % of Maximum power or voltage	Yes	Yes
User control of high frequency pulse as a % of maximum	Yes	Yes
User can control the unit's	Yes	Yes

PRODUCT COMPARISON TABLE		
Characteristic/Function	**Veinwave device (predicate)**	**VeinGogh Instrument**
pulse amplitude		
User controls the pulse amplitude and pulse duration for thermocoagulation	Yes	Yes
Dissipated Power at 100% Output Power with 300ms pulse & 1000 Ohm load	1.35W	1.35W
Dissipated Power at Typical Treatment Power, assuming 1000 Ohms	0.66W	0.66W
Range of Peak to Peak Pulse Amplitude	80Vpp to 502Vpp	98Vpp to 205Vpp (+/- 10%)
Output Voltage Increases at Low Settings	Yes	No
No user control or measurement of power as found in "electrosurgical devices"	Yes	Yes
Relative power settings from 5% to 100%	Yes	Yes
Power setting has a pre-set or default	Yes	Yes
Maximum power setting identified	Yes	Yes
No claim made to linearity of power setting	Yes	Yes
Testing documents non-linearity of power settings	Yes	Yes
Testing of optimum or default setting as Vpp +/- 4%	207	205
Testing of lowest stated or recommended as Vpp +/- 4%	144	143
Number of settings based on the range of power settings from lowest listed or recommended	3	14
Nearly identical treatment output signals at 100ms burst	Yes	Yes
Nearly identical treatment output signals at 200ms burst	Yes	Yes
Nearly identical treatment output signals at 400ms burst	Yes	Yes
Nearly identical treatment output signals at 800ms burst	Yes	Yes
Power setting displayed	Yes	Yes

PRODUCT COMPARISON TABLE		
Characteristic/Function	**Veinwave device (predicate)**	**VeinGogh Instrument**
Labeling of Relative Output Settings & Relative Voltages on Device & User Manual	No	Yes
Display of pulse duration in 0.1 second	Yes	Yes
Control of pulse duration in 0.1 second increments	Yes	Yes
User reset to zero seconds	Yes	Yes
Measured pulse shapes at low Vpp are similar	Yes	Yes
Measured pulse shapes at medium Vpp are similar	Yes	Yes
Measured pulse shapes at high Vpp are similar	Yes	Yes
Pre-set or default pulse duration in seconds	0.2	0.2
Range of pulse duration settings	0.1 second – 0.8 second	0.1 second to 0.8 second
Display of # of pulses in treatment session	Yes	Yes
Pulse activation causes a acoustic "beep" or short audio tone	Yes	Yes
Pulse duration displayed	Yes	Yes
Timer display of length of time device has been in "run" mode	Yes	Yes
Reset timer to zero time	Yes	Yes
Display how many pulses the device has performed	Yes	Yes
Reset display of pulses to zero	Yes	Yes
Set "Standby" mode – display current status	Yes, "Off" is their standby	Yes
Set "Run" mode – display the current status	Yes	Yes
Auto-Pulse Enable	No auto-pulse functionality	User activated software which provides the user with an output pulse with a user defined adjustable delay between pulses
Auto-Pulse Disable	No auto-pulse functionality	User inactivates software functionality
Ballet Needle Holder (stylus) Cable and Cord	Yes	Identical
Ballet K3 Needles	Yes	Identical
Ballet K2 Needles	Yes	Identical
Ballet K3/K2 Gold Needles	Yes	Identical

Discussion of Differences in Characteristics between the VeinGogh Instrument and the Predicate Device

The **VeinGogh** instrument is certified to IEC 60601-2-2, Edition 5.0 2009-02 Medical Electrical Equipment Part 2-2. The instrument has passed UL 94 Flammability testing. The Submitter believes the electrical safety certification and flammability testing provides users with assurance the **VeinGogh** instrument is safe to use as specified and as intended.

The **VeinGogh** instrument's power supply is an off-the-shelf medical rated Astrodyne MKK 40D-23 24V output device. The predicate's power supply is an in-house designed with 100V output. The Submitter believes that the **VeinGogh** instrument's power supply is as safe or safer than the predicate's power supply. The **VeinGogh** instrument has dual capacitors, while the predicate device has a single capacitor. The Submitter believes that dual capacitors provide the user with greater failure protection.

The **VeinGogh** instrument's typical maximum output voltage is 205 Volts +/- 10%, while the predicate device's maximum output voltage is 500 Volts. The Submitter believes that the lower maximum voltage provides the user with greater safety during treatment sessions.

Both the **VeinGogh** instrument and the predicate device have proprietary firmware/software.

The **VeinGogh** instrument has a color LCD display, while the predicate device has a monochrome display. The Submitter does not believe that this difference is significant or provides any significant advantage to either device.

The **VeinGogh** instrument's range of peak to peak pulse amplitudes is 98VPP to 205Vpp, while the predicate device's peak to peak range is 80Vpp to 502Vpp. The Submitter believes that the lower peak to peak amplitude range provides the user with greater safety during treatment sessions.

The **VeinGogh** instrument's output voltage increases throughout the typical useful range of power settings, while the predicate device has noticeable dip in output voltages for the first setting, 5% and experiences lower output voltages at both 10% and 15%. Both units exhibit either small, similar or identical output voltages at power settings above 80%. The Submitter believes that the predicate's dip in output voltage many not be expected by users of their device.

The **VeinGogh** instrument has 20 power settings from the lowest listed or recommended to the highest, the predicate device has only 3 power settings from the lowest listed or recommended to the highest recommended settings. The Submitter believes that this greater range of power settings provides the user with a more sophisticated range of output voltages for use during treatment.

The **VeinGogh** instrument has a user activated software feature called "Auto-Pulse," which can be enabled or disabled. Auto-Pulse provides the user with an output pulse with a user defined adjustable delay between pulses settings. The predicate device has no similar characteristic or feature. The Submitter believes that the Auto-Pulse feature provides users with a more efficient treatment protocol.

NON-CLINICAL PERFORMANCE DATA TESTING AND REVIEW - as required by 807.92(b)(1)

Non-Clinical Testing

The submitted instrument has undergone significant verification and validation testing.

Verification testing included the bench testing of major electronic components of the instrument.

The firmware was developed by a contract supplier who has provided the firmware specifications requirements document and other firmware documentation. Firmware modules were subjected to verification testing.

Validation testing included testing of the finished instrument's intended use, requirements and confirmation that all identified hazards have been either eliminated or mitigated to an acceptable level.

The performance data records documents that the **VeinGogh** instrument met its stated requirements and design specifications as intended.

Animal and Clinical Testing

The submitter believes that both the predicate instrument and the submitted instrument have the same indications for use, the same or similar design features and functions, which negates a requirement for the submission of animal or clinical testing. Those few characteristics that the submitted instrument has that are not found in the predicate device are typically the result of the interaction with potential users and their desire for functionality that improves their use of this technology and are not significant differences.

Electrical Safety Testing

The submitter claims and documents conformance to:

1. IEC 60601-2-2, 4th Edition, 2006, Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment.
2. EN 60601-1-2:2007/IEC 60601-1-2:2007 (Medical Electrical Equipment – collateral standard: electromagnetic compatibility – requirements.
3. EC 60601-2-2:2006 Medical Electrical Equipment – Particular requirement for the safety of high frequency surgical equipment – (EMC testing only)
4. EN 55011:2007/A2:2007/CISPR 11:2003, Group 2, Class B, 2 pages.

Plastic Flammability

The submitter claims and documents conformance to UL 94 Tests for Flammability of Plastic Materials for Parts in Instruments and Appliances, Fifth Edition, Dated October 26, 1996; including revisions through October 21, 2010.

Testing Summary Claim

Refine USA, LLC claims that the submitted **VeinGogh** instrument's EMC, Electrical Safety testing and Flammability testing data, further documents the submitter's claim of safety and substantial equivalence.

SUBSTANTIAL EQUIVALENCE SUMMARY – as required by 807.92.(b)(3)

The submitted instrument, **Vein-Gogh**, has the same indications for use as the predicate instrument; the **Veinwave/TC3000** instrument manufactured by **Newlands Clinical Trials, Ltd.**, Bolton, United Kingdom, and cleared under **K083352.**

For the most part, the **VeinGogh** instrument has the identical or very similar technological characteristics as the predicate device. The submitted instrument does not introduce any new indications for use and will perform in a substantially equivalent manner as the predicate device. Those few characteristics that the Submitted instrument has that are not found in the predicate device are typically the result of the interaction with potential users and their desire for functionality that improves their use of this technology.

However, while the submitter believes the characteristics are sufficiently precise to assure equivalence, the submitter has carried out validation, conformance to a number of International and National standard, and performance testing to further document substantial equivalence.

CONCLUSION – as required by 907,.92(b)(3)

This 510(k) submission documents that the **VeinGogh** instrument is substantially equivalent to the predicate **Veinwave/TC3000** instrument.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY - 8 2012

Refine USA, LLC
% Mr. Brian Smith
President
340 3rd Avenue South, Suite C
Jacksonville Beach, Florida 32250

Re: K112334
Trade/Device Name: VeinGogh™ instrument
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: Class II
Product Code: ONQ
Dated: April 11, 2012
Received: April 23, 2012

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K112334**

Device Name: **VeinGogh™ instrument**

Indications for Use:

The **VeinGogh** device is intended for the treatment of lower limb spider vein or telangiectasia by thermocoagulation..

Prescription Use ___X___ or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112334

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